OCT - 6 2011

510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

A. Name and Address of Applicant

Avinger, Inc.
400 Chesapeake Drive
Redwood City, CA 94063

B. Contact Person

Sevrina Ciucci
Regulatory Affairs Consultant
(408) 316-4837

C. Date Prepared

September 2, 2011

D. Device Name

Trade Name:	Wildcat 5F Guidewire Support Catheter (Kittycat 2)
Common Name:	Guidewire Support Catheter
Classification Name:	Percutaneous Catheter

E. Device Classification

Classification:	21 CFR §870.1250
Product Code:	DQY
Device Class:	Class II

F. Predicate Device

The Avinger Wildcat 5F Guidewire Support Catheter (Kittycat 2) is substantially equivalent to the Avinger Wildcat 5F Guidewire Support Catheter (K101647).

G. Device Description

The Wildcat 5F Guidewire Support Catheter (Kittycat 2) is a 5F sheath and 0.014" guidewire compatible over-the-wire device. It consists of a catheter shaft with handle assembly at the proximal end and an atraumatic distal tip. The catheter is available in a working length of 150 cm. A locking luer connector at the proximal end provides entry to a lumen that supports and facilitates movement of a guidewire. The catheter has been irradiated for sterility and is intended for single use only.

H. Intended Use

The Wildcat 5F Guidewire Support Catheter (Kittycat 2) is intended to be used to support steerable guidewires in accessing discrete regions of the peripheral vasculature. It may be used to facilitate placement and exchange of guidewires and other interventional devices. It may also be used to deliver saline or contrast.

I. Substantial Equivalence

The Avinger Wildcat 5F Guidewire Support Catheter (Kittycat 2) is substantially equivalent to the Avinger Wildcat 5F Guidewire Support Catheter (K101647). The subject and predicate devices have the same mechanism of action (manual advancement) and perform the same function (access discrete regions of the peripheral vasculature). The primary differences between the subject and predicate device consist of an increased device working length and modifications to the Distal Tip deflection mechanism. The Slider based Distal Tip deflection mechanism was eliminated in favor of a pre-shaped Distal Tip. This modification required changes to the Distal Tip Scaffold, Distal Tip / Torque Shaft attachment, and Driveshaft construction. In addition, a change to the Fluid Seal Tube dimensions located in the Handle was made for ease of manufacturing purposes. The changes to the Wildcat 5F Guidewire Support Catheter cleared under K101647 results in no significant changes to technological characteristics and does not raise any new issues of safety or effectiveness.

J. Non-Clinical Performance Data

The following non-clinical testing was conducted to support a determination of substantial equivalence to the predicate device.

• Visual and Dimensional Verification	• Spiral Blade Functional Testing
• Tensile Testing	• Coating Friction Testing
• Torque Testing	• Biocompatibility
• Guidewire advancement	• In Vitro Simulated Use Testing
• Device Advancement	• Packaging Testing
• Tip Deflection Testing	• Shipping Testing
• Device leak testing	• Shelf Life Testing
• Luer Leak Testing	• Sterility Testing
• Flexibility/Trackability	

The above testing confirmed that the Wildcat 5F Guidewire Support Catheter (Kittycat 2) performs according to the stated intended use. All data fell well within pre-determined product specifications and external standard requirements.

Results of non-clinical testing demonstrated that the Wildcat 5F Guidewire Support Catheter (Kittycat 2) is substantially equivalent to the predicate device for its intended use.

K. Conclusions

The Avinger Wildcat 5F Guidewire Support Catheter (Kittycat 2) has been carefully compared to a legally marketed device with respect to intended use and technological characteristics. In addition, non-clinical testing was conducted to validate the performance of the device and ensure the Wildcat 5F Guidewire Support Catheter (Kittycat 2) functions as intended and meets design specifications. The comparison and non-clinical results demonstrate that the device is substantially equivalent to the predicate device for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Avinger, Inc.
c/o Sevrina Ciucci
400 Chesapeake Dr.
Redwood City, CA 94063

OCT - 6 2011

Re: K112579
Trade/Device Name: Wildcat 5F Guidewire Support Catheter (Kittycat 2)
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II (two)
Product Code: DQY
Dated: September 2, 2011
Received: September 6, 2011

Dear Ms. Ciucci:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K112579

Device Name: Wildcat 5F Guidewire Support Catheter (Kittycat 2)

Indications for Use:

The Wildcat 5F Guidewire Support Catheter (Kittycat 2) is intended to be used to support steerable guidewires in accessing discrete regions of the peripheral vasculature. It may be used to facilitate placement and exchange of guidewires and other interventional devices. It may also be used to deliver saline or contrast.

Prescription Use ___X___ **Or** **Over-The-Counter Use** _____

(per 21 CFR 801.109)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K112579